Osteoporosis and Vertebral Compression (Spinal) Fractures Fact Sheet

About Osteoporosis

- Osteoporosis is estimated to affect 200 million women worldwide.[1]
- Worldwide, osteoporosis causes more than nine million fractures annually, resulting in an osteoporotic fracture every three seconds.[1]
- A recent report issued by the Surgeon General noted that by 2020, one in two Americans over age 50 will be at risk for fractures from osteoporosis and low bone mass.[2]
- Although prevalent, 75 percent of women and 90 percent of men with a high likelihood of developing osteoporosis are not investigated. [3]
- Up to 80 percent who have already had at least one osteoporotic fracture are neither identified nor treated.[3]
- Overall, 61 percent of osteoporotic fractures occur in women, with a female-to-male ratio of 1.6.[4]
- A prior fracture is associated with an 86 percent increased risk of any fracture.[5]
- In 2005, osteoporosis-related fractures cost the U.S. health care system about $17 billion per year.[6]
- Osteoporosis takes a huge personal and economic toll. In Europe, the disability due to osteoporosis is greater than that caused by cancers (with the exception of lung cancer) and is comparable to or greater than that lost to a variety of chronic non-communicable diseases, such as rheumatoid arthritis, osteoarthritis, chronic obstructive pulmonary disease (COPD) and ischemic heart disease.[4]

About Vertebral Compression (Spinal) Fractures

- Osteoporosis causes more than 700,000 spinal fractures each year in the U.S. – more than twice the annual number of hip fractures[1] – accounting for more than 100,000 hospital admissions and resulting in close to $1.5 billion in annual costs.[8]

- Vertebral fractures are the most common osteoporotic fracture, yet approximately two-thirds are undiagnosed and untreated. [1]

- Approximately 20 to 25 percent of Caucasian women and men over 50 years old have a prevalent vertebral fracture. [1]

- One in five women with a vertebral fracture will sustain another within 12 months. [1]

- Vertebral fractures lead to severe spinal deformity, back pain, loss of height, reduced mobility, depression and increased number of bed days[1]

- The impact vertebral fractures have on quality of life can be profound, as a result of loss of self-esteem, isolation and depression. Vertebral fractures also significantly impact activities of daily living.[1]

- Vertebral fractures are associated with a 20 percent reduction in QALY (quality adjusted life year) in the first 12 months, and a 15 percent reduction in the first two years since time of fracture. [9]

For more information on Balloon Kyphoplasty, go to:
www.kyphon.com
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End Notes

1. Bouxsein , M. L., & Genant, H. K. (2010). The Breaking Spine. *International Osteoporosis Foundation.*
2. U.S. Department of Health and Human Services (2004). "=By 2020, One In Two Americans Over Age 50 Will Be At Risk For Fractures From Osteoporosis Or Low Bone Mass. U.S. Department of Health and Human Services, Office of the Surgeon General. Retrieved from http://archive.hhs.gov/news/press/2004pres/20041014.html
3. Nguyen, et al (2004). Osteoporosis: Underrated, Underdiagnosed and Undertreated. *The Medical Journal of Australia.* 2004; 180: S18-22.
4. Johnell O and Kanis JA (2006) An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. *Osteoporosis International* 17:1726.
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7. Kanis, et al (1997). Guidelines for Diagnosis and Management of Osteoporosis. *Osteoporosis International*: 1997; 7: 390-406.

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9. Tosteson, et al. (2001). Impact of Hip and Vertebral Fractures on Quality-Adjusted Life Years. *Osteoporosis International.* 2001; 12: 1042-1049

**BKP short and long-term claims are also summarized in the Tab 10 document submitted to FDA.

KYPHON® BALLOON KYPHOPLASTY BACKGROUNDER

The Condition: Spinal Fractures
Osteoporosis is the most widespread degenerative disease in the developed world. Globally, an osteoporotic fracture is estimated to occur every three seconds with spinal fractures being the most common.[1]

Osteoporosis causes more than 700,000 spinal fractures each year in the U.S., more than twice the annual number of hip fractures.[2,3]

Spinal fractures can also be caused by cancer, the most common forms being multiple myeloma, breast, lung and prostate.[4] According to the Multiple Myeloma Research Foundation, the majority of patients with multiple myeloma—some 70 to 95 percent—experience progressive bone destruction, particularly in the spine, because rapidly growing myeloma cells push normal bone-forming cells aside.

Although spinal osteoporotic fractures are the most common type of fragility fracture, they remain largely undiagnosed and untreated. Up to two-thirds are not recognized by doctors.[3] Untreated, as many as one in five women with a spinal fracture will sustain another within 12 months, often referred to as the "fracture cascade." Just 40 percent of older women and less than 20 percent of men with spinal fractures visible on X-ray are tested for osteoporosis.[3]

Some spinal fractures may collapse immediately while others collapse over time, resulting in a condition called kyphosis, or rounded back. Kyphosis, signified by the so-called dowager's hump, compresses the chest and abdominal cavity, which can result in serious negative health and quality of life (QOL) consequences such as:

Health Consequences
- Increased risk of falls and fractures[3]
- Increased patient disability[3]
- Height loss[3]
- Chronic and acute pain[3]
- Reduced quality of life

Quality of Life Consequences

- Reduced mobility including slower walking pace and use of walking aids[3]
- Loss of self-esteem[3]
- Social isolation[3]
- Depression[3]

The current standard of care for a spine fracture is bed rest, pain medication, physical therapy, bracing and local steroid injections.[2] However, this approach does little to treat or prevent the formation of a kyphosis deformity and the associated "downward spiral" of negative consequences.

Balloon Kyphoplasty Outcomes

Balloon Kyphoplasty is a minimally invasive treatment that corrects vertebral deformity and stabilizes VCFs, thereby providing pain relief.

Short-Term Benefits	Long-Term Benefits
• Vertebral Height Restoration • Significant improvement in quality of life[3] • Significant improvement in mobility, including the ability to perform daily activities such as walking, hobbies and work[7] • Low complication rate (<1%)[7] • Reduction in back pain[3]	• Vertebral Height Restoration • Maintenance of improvement in quality of life[3] • Maintenance of improvement in mobility, including the ability to perform daily activities such as walking, hobbies and work[7] • Maintenance of reduction in back pain[3]

Restoring normal spine anatomy can help a patient avoid the negative health and QOL consequences of a rounded back.

The Balloon Kyphoplasty Procedure

Through a pair of small incisions each approximately 1 cm in length, the specialty physician uses a needle and cannula to create a small pathway into each side of a fractured vertebral body. A small balloon is guided through each cannula into the vertebra. Each balloon is carefully inflated in an attempt to raise the collapsed vertebra and return it to its normal position. Inflation of the balloon creates a void (cavity) in the vertebral body.

Once the vertebra is in the correct position, the balloons are deflated and removed. The resultant cavities are filled with bone cement forming an "internal cast" to support the surrounding bone and prevent further collapse.

The Balloon Kyphoplasty procedure typically takes about one hour per fracture and may be performed in an outpatient setting. The procedure can be done using either local or general anesthesia; the specialty physician will determine the most appropriate method, based on the patient's overall condition.

In most cases, Medicare provides coverage for Balloon Kyphoplasty. Other insurance plans often also cover the procedure. Although the complication rate with KYPHON® Balloon Kyphoplasty has been demonstrated to be low, as with most surgical procedures, there are risks associated with the procedure, including serious complications. This procedure is not for everyone. A prescription is required. Patients should consult their physician for a full discussion of risks and whether this procedure is right for them.

Since its founding in 1994, Kyphon has been dedicated to improving patient quality of life by revolutionizing the practice of medicine. A recognized global leader in restoring spinal function with minimally invasive therapies, Kyphon maintains its commitment to ongoing research, innovative product development and advanced professional and patient education. Kyphon was acquired by Medtronic, Inc. in November 2007 and is now part of the Medtronic Spinal and Biologics business.

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End Notes

1. Osteoporosis (n.d.) In International Osteoporosis Foundation. Retrieved from http://www.iofbonehealth.org/osteoporosis
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Vertebral Compression Fractures and KYPHON® BALLOON KYPHOPLASTY Q&A

What is osteoporosis?
Osteoporosis is the most widespread degenerative disease in the developed world. Globally, an osteoporotic fracture is estimated to occur every three seconds, with vertebral compression (spinal) fractures (VCFs) being the most common.[1,2]

What are vertebral compression fractures and how common are they?
Vertebral compression fractures are a collapse in the vertebra. Osteoporosis causes more than 700,000 spinal fractures each year in the U.S., more than twice the annual number of hip fractures.[3]

What causes vertebral compression fractures?
VCFs are mainly the result of osteoporosis, but they can also be caused by cancer – the most common forms being multiple myeloma, breast, lung and prostate.[4] According to the Multiple Myeloma Research Foundation, the majority of patients with multiple myeloma experience progressive bone destruction, particularly in the spine, because rapidly growing myeloma cells push normal bone-forming cells aside.[5]

Are vertebral compression fractures widely diagnosed?
Although osteoporotic fractures of the spine are the most common type of fragility fracture, they remain largely undiagnosed and untreated. Up to two-thirds are not recognized by doctors. Untreated, as many as one in five women with a spinal fracture will sustain another within 12 months, often referred to as the "fracture cascade." Just 40 percent of older women and less than 20 percent of men with spinal fractures visible on X-ray are tested for osteoporosis.[3]

What is kyphosis?
Some spinal fractures may collapse immediately while others collapse over time, resulting in a condition called kyphosis, or rounded back. Kyphosis, signified by the so-called dowager's hump, compresses the chest and abdominal cavity, which can result in serious negative health and quality-of-life (QOL) consequences such as:

Health Consequences	Quality of Life Consequences
• Increased risk of falls and fractures[3] • Increased patient disability[3] • Height loss[3] • Chronic and acute pain[3]	• Reduced mobility, including slower walking pace and use of walking aids[3] • Loss of self-esteem[3] • Social isolation[3] • Depression[3]

How are VCFs treated?
The current standard of care for a spine fracture is bed rest, pain medication, physical therapy, bracing and local steroid injections.[3] However, this approach does little to treat or prevent kyphosis.

What is Balloon Kyphoplasty?
Balloon Kyphoplasty is a minimally invasive treatment that corrects vertebral deformity and stabilizes VCFs, thereby providing pain relief.

How is the Balloon Kyphoplasty procedure performed?
Through a pair of small incisions each approximately 1 cm in length, the specialty physician uses a needle and cannula to create a small pathway into each side of a fractured vertebral body. A small balloon is guided through each cannula into the vertebra. Each balloon is carefully inflated in an attempt to raise the collapsed vertebra and return it to its normal position. Inflation of the balloon creates a void (cavity) in the vertebral body.

Once the vertebra is in the correct position, the balloons are deflated and removed. The resultant cavities are filled with bone cement forming an "internal cast" to support the surrounding bone and prevent further collapse.

How long does Balloon Kyphoplasty take?
The Balloon Kyphoplasty procedure typically takes about one hour per fracture and may be performed in an outpatient setting. The procedure can be done using either local or general anesthesia; the specialty physician will determine the most appropriate method, based on the patient's overall condition.

What are the benefits of Balloon Kyphoplasty?
Studies report the following benefits:

**Short-Term Benefits	**Long-Term Benefits
• Vertebral height restoration[4] • Significant improvement in quality of life[4,6] • Significant improvement in mobility, including the ability to perform daily activities such as walking, hobbies and work[6] • Low complication rate (roughly equivalent to non-surgical management)[7] • Reduction in back pain[4,6]	• Vertebral height restoration[8] • Maintenance of improvement in quality of life[6] • Maintenance of improvement in mobility, including the ability to perform daily activities such as walking, hobbies and work[6] • Maintenance of reduction in back pain[6]

Restoring normal spine anatomy can help a patient avoid the negative health and QOL consequences of a rounded back.

Is Balloon Kyphoplasty covered by insurance?
In most cases, Medicare provides coverage for Balloon Kyphoplasty. Other insurance plans often also cover the procedure. Although the complication rate with KYPHON® Balloon Kyphoplasty has been demonstrated to be low, as with most surgical procedures, there are risks associated with the procedure, including serious complications. This procedure is not for everyone. A prescription is required. Patients should consult their physician for a full discussion of risks and whether this procedure is right for them.

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End Notes

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